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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT W. LANGLEY, THOMAS J. FELT, GEERT VAN
WAEG, and MARLENE ADELE BAINBRIDGE

Appeal 2009-008624
Application 10/680,950
Technology Center 3700

Decided: September 18, 2009

Before TONI R. SCHEINER, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of processing blood, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification discloses that “the occurrence of blood vessel infiltration caused by rapid changes in access blood vessel pressure is a common problem experienced by virtually all apheresis methods known in the art” (Spec. 3: 10-12). “For example, a sharp increase in blood vessel pressure over a short time may cause a perforation in the wall of the blood vessel, commonly referred to as vein ‘blow out.’ Also a sharp decrease in blood vessel pressure over a short time may cause the walls of the blood vessel to collapse.” (*Id.* at 3: 24-26.)

The Specification discloses “methods and devices for processing blood which minimize changes in the pressure of an access blood vessel and suppress the incidence of access blood vessel infiltration” (*id.* at 4: 28-30).

Claims 1-53 and 56-68 are pending and on appeal. Claims 25-27, the only independent claims, read as follows:

25. A method of processing blood, comprising the steps of:
- determining the total blood volume of a subject undergoing a blood processing procedure;
 - removing blood from said subject at a selected removal flow rate thereby generating removed blood, wherein said selected removal flow rate is adjusted during operation of the blood processing based on said total blood volume;
 - processing said removed blood, thereby generating processed blood including at least one return component; and
 - returning at least a portion of said return component to said subject at a return flow rate.

26. A method of processing blood, comprising the steps of:
determining the total blood volume of a subject undergoing a blood processing procedure;
removing blood from said subject, thereby generating removed blood;
processing said removal blood, thereby generating processed blood including at least one return component; and
returning at least a portion of said return component to said subject at a selected return flow rate, wherein said selected return flow rate is adjusted during operation of the blood processing procedure based on said total blood volume of said subject.

27. A method of processing blood, comprising the steps of:
determining the total blood volume of a subject undergoing a blood processing procedure;
removing blood from said subject at a removal flow rate thereby generating removed blood, wherein said removal flow rate is adjusted during operation of the blood processing procedure based on said total blood volume;
processing said removed blood, thereby generating processed blood including at least one return component; and
returning at least a portion of said return component to said subject at a return flow rate, wherein said return flow rate is adjusted during operation of the blood processing procedure based on said total blood volume of said subject.

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

- Claims 1-12, 14-15, 17-40, 42-45, 47-50, and 67 based on Holmes¹ and Elgas² (Ans. 3); and
- Claims 13, 16, 41, 46, 51-53, 56-66, and 68 based on Holmes, Elgas, and Pierce³ (Ans. 9).

¹ Holmes et al. (US 6,179,801 B1, Jan. 30, 2001).

² Elgas (US 5,980,465, Nov. 9, 1999).

OBVIOUSNESS

Issue

The Examiner has rejected claims 1-12, 14, 15, 17-40, 42-45, 47-50, and 67 as obvious in view of Holmes and Elgas. The Examiner finds that Holmes discloses the claimed methods except for limitation of adjusting the removal and/or return flow rates based on total blood volume (*id.* at 3-4). The Examiner finds that Elgas discloses “increasing fluid flow to the patient in the event of total blood volume decrease,” and that this teaching “suggests to one of ordinary skill in the art other steps, such as adjusting blood withdrawal rate, would be within the range of reasonable steps taken to maintain the patient’s total blood volume” (*id.* at 4). The Examiner concludes that it would have been obvious “to use the suggestion of the Elgas disclosure with regard to maintaining patient total blood volume through fluid flow rate adjustments in the apheresis procedure disclosed by Holmes” (*id.*).

Appellants contend that “[n]owhere does Elgas disclose adjusting the blood return flow rate or removal flow rate of the device itself. Thus, even if one skilled in the art were to combine the teachings in Holmes and Elgas, the result would not lead to the methods as presently claimed.” (App. Br. 10.)

The issue presented in this appeal is: Did the Examiner err in concluding that Elgas would have suggesting adjusting the blood removal or return rate, based on total blood volume, during Holmes’ apheresis procedure?

³ Pierce et al. (US 6,730,054 B2, May 4, 2004).

Findings of Fact

1. Holmes discloses “methods and apparatus which may be incorporated into an apheresis system (e.g., blood component collection, therapeutic)” (Holmes, col. 1, ll. 11-13).

2. Holmes discloses that the graphical user interface of its system (col. 51, l. 8) includes a “donor/patient data screen 788 which includes a sex-type button 792, a height button 796, and a weight button 808,” with which the operator enters the donor/patient’s sex, height, and weight (*id.* at col. 56, ll. 46-54).

3. Holmes discloses that the “information entered by the operator on the donor/patient data screen 788 is used to calculate, for instance, the donor/patient’s 4 total blood volume” (*id.* at col. 56, ll. 61-63).

4. Holmes discloses that the “donor/patient’s 4 total blood volume may be utilized in the determination of various parameters associated with the apheresis procedure and/or in the estimation of the number of blood components which are anticipated to be collected in the procedure” (*id.* at col. 56, l. 65 to col. 57, l. 2).

5. The Examiner finds that “Holmes fails to disclose the step of adjusting a removal and/or flow rate during the blood processing procedure based on the total blood volume” (Ans. 4).

6. Elgas discloses that during cardiac surgery a heart-lung machine circulates and oxygenates the patient’s blood (Elgas, col. 1, ll. 18-22).

7. Elgas discloses that “the introduction of anesthetic intravenous (IV) fluids, the natural action of the patient’s kidneys, and the loss of blood during surgery all produce significant variations in the volume and

composition of the fluid circulating in the patient's circulatory system" (*id.* at col. 1, ll. 33-38).

8. Elgas discloses that a drop in a patient's blood pressure during surgery "might indicate either a decrease in fluid volume from either blood loss or kidney activity, or an expansion of blood vessels from physiological causes. In the former case, increased IV fluid flow rate or transfusion of blood would be called for; in the latter case, the remedy would be constricting medication." (*Id.* at col. 1, ll. 42-47.)

Principles of Law

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

"We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).

Analysis

Holmes discloses an apheresis method that includes calculating the donor/patient's total blood volume. Holmes discloses that the total blood volume "may be utilized in the determination of various parameters associated with the apheresis procedure" (FF 4) but does not disclose that those parameters include the blood removal or return rate, nor does it suggest adjusting the removal or return rate during the apheresis procedure.

Elgas discloses that decreased fluid volume during cardiac surgery may call for "increased IV fluid flow rate or transfusion of blood" (FF 8). Elgas does not, however, suggest adjusting the rate at which the patient's blood is circulated (i.e., removed and returned), whether based on a change in blood volume or any other parameter.

The Examiner points out that, in Elgas' system, "blood is withdrawn and returned via a variable-speed roller pump which may be accurately controlled, which suggests adjustability of flow rate" (Ans. 14). The Examiner reasons that, combined with Elgas' disclosure that a drop in blood volume may be addressed by increasing IV fluid flow rate or blood transfusion,

[i]t follows naturally that if a patient's blood volume changes, one using the Elgas device would adjust variable speed pump 22 to adjust the blood withdrawal and return rates based on such measurement. The Examiner is relying on the Elgas reference to teach a) the criticality of patient blood volume and b) that adjusting fluid flow rates is a recognized way of responding to changes in blood volume.

(*Id.*)

We do not agree with the Examiner's interpretation of Elgas' disclosure. Elgas teaches that adjusting the flow rate of IV fluids is a

recognized way of responding to decreased blood volume. That is, Elgas simply says that if the patient's blood volume goes down during surgery, the rate at which IV fluid is being pumped into the patient should be increased. The claims, however, require that the rate at which *blood* – not IV fluid – is removed from or returned to the body is adjusted based on the total blood volume.

Elgas does not disclose changing the rate at which blood is circulated by its system during surgery. The Examiner has not provided evidence or reasoning sufficient to show that adjusting the blood removal or return rate based on total blood volume, as required by the claims on appeal, would have been obvious to a person of ordinary skill in the art based on Holmes and Elgas.

The Examiner also rejected claims 13, 16, 41, 46, 51-53, 56-66, and 68 based on Holmes, Elgas, and Pierce (Ans. 9). This rejection, however, relies on Holmes and Elgas, as discussed above, to make obvious the limitations of independent claims 25-27. Because we conclude, for the reasons discussed above, that Holmes and Elgas would not have made obvious the methods of claims 25-27, the rejection based on Holmes, Elgas, and Pierce is also reversed.

Conclusion of Law

The Examiner erred in concluding that Elgas would have suggesting adjusting the blood removal or return rate, based on total blood volume, during Holmes' apheresis procedure.

SUMMARY

We reverse the rejection of claims 1-12, 14, 15, 17-40, 42-45, 47-50, and 67 as obvious in view of Holmes and Elgas; and the rejection of claims 13, 16, 41, 46, 51-53, 56-66, and 68 as obvious in view of Holmes, Elgas, and Pierce.

REVERSED

Ssc:

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